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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,262

11/13/2006

Venkata Satya Nirogi Ramakrishna

SUB 0007 US

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10/09/2009

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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

10/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,262	Applicant(s) RAMAKRISHNA ET AL.	
	Examiner Golam M. M. Shameem	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/21/09; 01/06/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a 371 of PCT/IN03/00393 12/16/2003, is acknowledged.

Status of Claims

Claims 1-17 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on August 11, 2009 and that has been entered.

Claims 4-6 and 9-17 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 04/21/2009, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-2 and 7, drawn to a compound of the formula (I) and the elected species as set forth found in Example 6 on page 43 of the specification, with traverse is acknowledged. Applicant's arguments (to withdraw restriction requirements) have been fully considered and found partially persuasive and therefore, Examiner has agreed to modify the restriction requirements to include and examine Group II, claims 3 and 8 together with the elected invention of Group I, because they commensurate within the scope of the elected invention.

However, the Examiner respectfully disagrees with the Applicant's other arguments at this time because the Invention groups III-VI differ materially in structure and in element from

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each other and therefore, are capable of supporting their own patents. The invention Groups I-VI each relate to a set of structurally diverse and dissimilar compounds [having different variable groups, which are attached directly and indirectly to the formula (I)], process for the preparation and their methods of use, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. The core does not define a contribution over the art. The ring structure of formula (I) is further substituted by different variables such as R₁, R₂, n, and A etc, which are broadly defined and when the compound of formula (I) is taken as a whole, a plethora of vastly different compounds are possible. Thus, these features are not considered 'special technical features' under PCT rules 13.1 and 13.2. Hence, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

In addition, 35 U.S.C. 372 (b)(2) clearly states that unity of invention may be reexamined under 35 U.S.C. 121. Restriction was based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B (2)(V) when dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the Examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. If the Examiner finds one of the inventions unpatentable over the prior art the evidence or admission may be used in a rejection under 35 U.S.C. 103 (a) of the other invention. Nevertheless, Examiner may reconsider to rejoin one method of use claim commensurates in scope with the product claims when the case would be found in condition for allowance [provided that method of use claim is free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, since 35 U.S.C. 101 allows one patent per invention, the requirement for restriction (election of species) is still deemed sound and proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-4, 20 and 26 of co-pending Application

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No. 10/536,618 (US '618). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The compounds taught by co-pending application is similar to instant application because a reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since US '618 teaches the generic compounds and compositions which are similar to the instantly claimed invention.

The subject matter claimed in the instant application is fully disclosed and covered in co-pending Application No. 10/536,618. Therefore, the disclosure of US '618 application that teach many permutation and combinations (including various Markush variable substitutions, such as R₁, R₂, n, and A etc), which would easily place Applicant's invention in possession of the public at the time of Applicant's invention was filed. The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). Therefore, one having ordinary skill in the chemical art would consider the instantly claimed compounds of US '618 application as *prima facie* obvious and would be motivated to choose to make the preferred compounds (such as preparing a tetracyclic indoles by a ring closure or fusion reaction) in view of the known teaching in the art. The claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the reference as to be structurally obvious in the absence of any unobviousness or unexpected properties. Therefore, in the absence of objective evidence showing an unexpected result, the obviousness-type double patenting rejection is deemed to be proper.

Objections

The expressions “a polymorph” “ the prodrug” “or a solvate, or a hydrate” should be deleted from claim 2 (lines 22-25, page 51, and all other occurrences, if any), “bio-active metabolites” (claim 7, line 16, page 56) because the terms are undefined by Applicant’s disclosure.

The superfluous word “general” (recited in claim 1, line 1, page 48, and also in all other claims, if any) should be deleted.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) “Official” for papers that are to be entered into the file, and “Unofficial” for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be

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addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/

Primary Patent Examiner

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